

**510(k) SUMMARY**

AUG 7 2012

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**CONTACT NAME:** Paul Swift, Regulatory Affairs Specialist  
**DATE PREPARED:** August 7, 2012

**DEVICE TRADE NAME:** BD BACTEC Plus PRIME Aerobic/F

**DEVICE COMMON NAME:** Aerobic blood culture medium

**DEVICE CLASSIFICATION:** 21 CFR§866.2560, Class I

**PREDICATE DEVICE:** BD BACTEC PLUS Aerobic/F medium (K083572)

**INTENDED USE:**

The BD BACTEC Plus PRIME Aerobic/F medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC fluorescent series instruments.

**DEVICE DESCRIPTION:**

The sample to be tested is inoculated into one or more vials which are inserted into the BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO<sub>2</sub> produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO<sub>2</sub> present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

Resins have been described for the treatment of blood specimens both prior to and after their inoculation into culture media. Resins have been incorporated into BACTEC culture media to enhance recovery of organisms without a need for special processing.<sup>1,2,3,4</sup>

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<sup>1</sup> Wallis, C. et al. 1980. Rapid isolation of bacteria from septicemic patients by use of an antimicrobial agent removal device. J. Clin. Microbiol. 11:462-464.

<sup>2</sup> Applebaum, P.C. et al. 1983. Enhanced detection of bacteremia with a new BACTEC resin blood culture medium. J. Clin. Microbiol. 17:48-51.

<sup>3</sup> Pohlman, J.K. et al. 1995. Controlled clinical comparison of Isolator and BACTEC 9240 Aerobic/F resin bottle for detection of bloodstream infections. J. Clin. Microbiol. 33:2525-2529.

<sup>4</sup> Flayhart, D. et al. 2007. Comparison of BACTEC Plus blood culture media to BacT/Alert FA blood culture media for detection of bacterial pathogens in samples containing therapeutic levels of antibiotics. J. Clin. Microbiol. 45:816-821.

**DEVICE COMPARISON:**

**The BD BACTEC Plus PRIME Aerobic/F medium differs from the BD BACTEC Plus Aerobic/F (K083572) medium in the following ways:**

- The resin blend in the modified device consists of two hydrophobic adsorbing resins and one cationic exchange resin; whereas, the current legally marketed device contains one hydrophobic adsorbing resin and one cationic exchange resin.
- The percent of total resin blend per weight volume is lower in the modified device compared to the current legally marketed device.
- The concentration of sodium polyanetholsulfonate (SPS) is 0.085% per weight volume in the modified device; whereas, the current legally marketed device contains 0.05% SPS per weight volume.

**The BD BACTEC Plus PRIME Aerobic/F medium is similar to the BD BACTEC Plus Aerobic/F (K083572) medium in the following ways:**

- Both the new and predicate devices are used for the qualitative aerobic culture and recovery of microorganisms from human blood.
- Both devices are intended to be used with the BD BACTEC fluorescent-series of blood culture instruments.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same incubation and agitation parameters to both devices.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same growth and detection algorithms to both devices.
- Both devices are incubated at 35°C ( $\pm 1.5^{\circ}\text{C}$ ) for a period of up to 120 hours.
- Both devices incorporate resins for the adsorption of antimicrobials that may be present in clinical samples.
- Both devices incorporate a sensor that detects increases in CO<sub>2</sub> within the bottle as a result of organism growth. Both devices require a sample volume of 3 – 10 mL of blood.
- Both devices utilize 30 mL of enriched soybean casein digest broth as the growth medium.
- Both devices have a maximum blood to broth ratio of 1:4.
- Both devices are contained in glass vials.

## SUMMARY OF PERFORMANCE DATA

### Analytical Studies:

#### **Instrument Time to Detection**

A total of 333 paired sets were positive in both the new and predicate devices. There was no clinically relevant difference in recovery hours between the BD BACTEC Plus PRIME Aerobic/F blood culture medium and the predicate device. The estimated median TTD difference for the 333 positive sets is 0.92 hours (55 minutes). At the 10 to 100 CFU inoculum level, approximately 80% of 244 paired sets had a time to detection difference of less than 10%; 18% of the paired sets that had time to detection increases, and approximately 2% had time to detection decreases with the BD BACTEC Plus PRIME Aerobic/F medium when comparing to the predicate device.

The following organisms had a mean TTD difference that was more rapid in the predicate device: *Abiotrophia defectiva* (2.39 h), *Acinetobacter lwoffii* (0.97), *Cardiobacterium hominis* (3.11 h), *Haemophilus influenzae* (3.70 h), *Streptococcus sanguinis* (8.12 h), *Candida albicans* (0.75 h), *Enterococcus faecalis* (0.62 h), *Granulicatella spp.* (1 h), *Kingella kingae* (4.38 h), *Micrococcus luteus* (1.06 h), *Pediococcus acidilactici* (1.08 h) and *Streptococcus pneumoniae* (0.81 h). *Leuconostoc spp.* exhibited a mean TTD difference increase of 10.00 h compared to the predicate device (mean TTD of 69.21 h), an increase of 14.45% in the new device.

The data indicate that the effect of differences between the new and predicate devices on TTD under these test conditions was minimal and that the new device performs equivalently to the predicate device.

#### **Percent Recovery**

A total of 246 paired sets were evaluated in the Percent Recovery comparison. There was no significant difference in recovery between the BD BACTEC Plus PRIME Aerobic/F blood culture medium and the predicate device. Of those, 244 paired sets were positive in both the new and predicate devices (99.2%). The McNemar p-value for this data set equals 0.1573. The data indicate that the effect of differences between the new and predicate devices on percent recovery under these test conditions was not statistically significant and that the new device performs equivalently to the predicate device.

#### **False Positive Rate**

A total of 120 paired sets were used to execute this study. The 120 paired sets were comprised of 40 bottles from each of 3 lots. The paired sets were inoculated with fresh human blood at varying levels as specified by the test protocol and entered into the BACTEC blood culture instrument. It was expected that each bottle would be instrument-negative following the complete protocol (120 hours). All 120 paired sets completed the protocol with no positive results observed in either the new or predicate devices.

**False Negative Rate**

A total of 93 paired sets were evaluated for the determination of the False Negative Rate of the new device. There were two false negative results with the new device: *Kingella kingae* with 3 mL of blood (plate count 31 CFU). The *K. kingae* replicates that failed to recover in the new device were determined to be false negative based on the expected test results. Terminal subcultures of both replicates resulted in no growth. Subsequent testing of five isolates of *K. kingae*, including the false negative isolate noted above, under the same test conditions and over three lots all demonstrated growth and recovery as expected.

**Antimicrobial Neutralization Capability**

Both the new and predicate devices incorporate resins to enhance the recovery of microorganisms by adsorption of antibiotics in the blood sample. The new device incorporates a third resin for additional antimicrobial neutralization capability. Eleven drugs representative of their classes were evaluated at the MIC level of selected strains to demonstrate equivalent performance of the new device to the predicate device. At the MIC level, both devices demonstrated complete recovery (100%) in 10 out of 11 drug classes. With aztreonam, observed recovery rates were 55.6% and 66.7% for the BD BACTEC Plus PRIME Aerobic/F medium and the BD BACTEC Plus Aerobic/F medium, respectively. There was no statistically significant difference in recovery between the new and predicate devices observed during this evaluation (McNemar's test p-value = 0.5637).

A total of 150 paired sets were evaluated at the peak serum level. Concentrations of antimicrobials in test vials were at an average of 20x the MIC of the test organisms. The P-value for the peak serum level drug-bug challenge as calculated with the McNemar's test was less than ( $<$ ) 0.0001, indicating a significant difference between the new and predicate devices at peak serum levels, in favor of the new device.

The following antimicrobial classes were evaluated in this study:

- |                                       |   |                 |
|---------------------------------------|---|-----------------|
| • Aminoglycosides                     | • Carbapenems                                 | • Glycopeptides |
| • 3 <sup>rd</sup> gen. Cephalosporins | • Fluoroquinolones                            | • Tetracyclines |
| • 4 <sup>th</sup> gen. Cephalosporins | • Monobactams                                 | • Triazoles     |
| • Glycylcycline                       | • Penicillins / $\beta$ -lactamase inhibitors |                 |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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AUG 7 2012

Rc: k120994  
Trade Name: BD BACTEC Plus PRIME Aerobic/F  
Regulation Number: 21 CFR §866.2560  
Regulation Name: Microbial growth monitor  
Regulatory Class: Class I  
Product Codes: MDB  
Dated: July 27, 2012  
Received: July 30, 2012

Dear Mr. Swift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

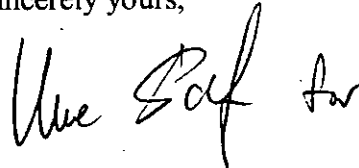
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat".

Sally A. Hojvat, M.Sc., Ph.D  
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